DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: FLOLAN®
Docket Nos. 95E-0418 and 95E-0419 #19

MAR 28 1996

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 4,338,325 and 4,883,812, filed by Glaxo Wellcome Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for FLOLAN®, the human drug product claimed by the patent.

The total length of the regulatory review period for FLOLAN® is 5,927 days. Of this time, 5,357 days occurred during the testing phase and 570 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 1, 1979.

   The applicant claims June 29, 1979, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 1, 1979, which was thirty days after FDA receipt of IND 16,459 on June 1, 1979.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 28, 1994.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for FLOLAN® (NDA 20-444) was initially submitted on February 28, 1994

3. The date the application was approved: September 20, 1995.

   FDA has verified the applicant's claim that NDA 20-444 was approved on September 20, 1995.

4,338,325

#20

Dated: March 28, 1996.
Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 96-8474 Filed 4-4-96; 8:45 am]
BILLING CODE 4160-01-F

[Docket Nos. 95E-0418 and 95E-0419]

Determination of Regulatory Review Period for Purposes of Patent Extension; FLOLAN®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FLOLAN® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product FLOLAN® (epoprostenol sodium). FLOLAN® is indicated for the long-term intravenous treatment of primary pulmonary hypertension in New York Heart Association Class III and Class IV patients. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for FLOLAN® (U.S. Patent Nos. 4,338,325 and 4,883,812) from Glaxo Wellcome Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibilities for patent term restoration. In letters dated February 8, 1996 (U.S. Patent No. 4,338,325), and February 22, 1996 (U.S. Patent No. 4,883,812), FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FLOLAN® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for FLOLAN® is 5,927 days. Of this time, 5,357 days occurred during the testing phase of the regulatory review period, while 570 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.355(i)) became effective*: July 1, 1979. The applicant claims June 29, 1979, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 1, 1979, which was 30 days after FDA receipt of IND 16,459 on June 1, 1979

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: February 28, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for FLOLAN® (NDA 20-444) was initially submitted on February 28, 1995.

3. *The date the application was approved*: September 20, 1995. FDA has verified the applicant's claim that NDA 20-444 was approved on September 20, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days (U.S. Patent No. 4,338,325) and 1,346 days (U.S. Patent No. 4,883,812) of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 4, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 2, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 28, 1996.
Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 96-8363 Filed 4-4-96; 8:45 am]
BILLING CODE 4160-01-F

Small Business Participation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a small business exchange meeting to create a dialogue between the small business community, particularly businesses owned and operated by minorities and women, and FDA officials. The meeting will be chaired by Arthur J. Beebe, Jr., Regional Food and Drug Director, Northeast Region, and it

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Rockville MD 20857

#21

MAR 21 1997

Re: FLOLAN (4,338,325)
Docket No. 95E-0418

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 4,338,325 filed by Glaxo Wellcome Inc. under 35 U.S.C. § 156. The patent claims the human drug product FLOLAN (4,338,325), New Drug Application (NDA) 20-444.

In the April 5, 1996, issue of the Federal Register (61 Fed. Reg. 15265), the Food and Drug Administration published it's determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before October 2, 1996, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: David J. Levy, Ph.D.
Patent Counsel, Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: David J. Levy, Ph.D.
Patent Counsel
Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709